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09/074,472	05/07/1998	MARK M. RICHTER	09481.0027	2284

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EXAMINER

FREDMAN, JEFFREY NORMAN

ART UNIT	PAPER NUMBER
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1637

DATE MAILED: 01/13/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/074,472	Applicant(s) RICHTER ET AL.	
	Examiner Jeffrey Fredman	Art Unit 1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 November 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 30-59 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 30-33 is/are allowed.
- 6) ☒ Claim(s) 34-42 is/are rejected.
- 7) ☒ Claim(s) 43-59 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 34-36, 38-40 and 42 are rejected under 35 U.S.C. 102(b) as being anticipated by Rajagopal et al (J. Photochem. Photobiol. A: Chem (1992) 69:83-89).

Rajagopal teaches a method for detecting an “analyte” in a sample composition (see table 3, where the analytes are the solvents) comprising the steps of:

(a) preparing an assay mixture comprising:

(i) said sample composition (see table 3, where the sample is the solvent, one of Acetonitrile, DMF, methanol or ethanol),

(ii) a first reagent comprising an ECL label having a chemical moiety that has electrochemical properties, which ECL label is capable of providing an observed ECL emission (see table 3 and page 83, column 2, where the ECL label ruthenium 4-alkyl, 4'-methyl-2,2'-bipyridine is used),

(iii) a second reagent having an ECL quenching moiety that, when in quenching contact with an ECL label, attenuates the observed ECL emission thereby providing a reduced ECL emission, said ECL quenching moiety comprising at least one benzene moiety (see page 83, column 2 and table 2,

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where phenols such as phenol are used for quenching in acetonitrile/water solutions)

(b) detecting a difference between the observed ECL emission and the reduced ECL emission, thereby confirming the presence of said analyte in the sample solution (see table 3, where increasing solvent concentrations resulted in quenching).

With regard to claims 35, 36, 38 and 39, Rajagopal teaches phenol and benzene carboxylic acid and carboxylate moieties (see table 2).

With regard to claims 40, 42, Rajagopal teaches an ECL reagent with Ruthenium 4-alkyl, 4'-methyl-2,2'-bipyridine (see table 3).

3. Claims 34-36, 38-40 and 42 are rejected under 35 U.S.C. 102(b) as being anticipated by Vera et al (J. Photochem. Photobiol. A: Chem (1993) 76:13-19).

Vera teaches a method for detecting an "analyte" in a sample composition (see table 3, where the analytes are the different pH solutions) comprising the steps of:

(a) preparing an assay mixture comprising:

(i) said sample composition (see table 1, where the sample is the different pH solutions),

(ii) a first reagent comprising an ECL label having a chemical moiety that has electrochemical properties, which ECL label is capable of providing an observed ECL emission (see table 1 and page 13, column 2, where the ECL label ruthenium bipyridine is used),

(iii) a second reagent having an ECL quenching moiety that, when in quenching contact with an ECL label, attenuates the observed ECL emission thereby providing a reduced ECL emission, said ECL quenching moiety comprising at least one benzene moiety (see table 1), where a variety of different phenols were used)

(b) detecting a difference between the observed ECL emission and the reduced ECL emission, thereby confirming the presence of said analyte in the sample solution (see table 1, where different pH resulted in quenching relative to other pH levels).

With regard to claims 35, 36, 38 and 39, Vera teaches phenol and benzene carboxylic acid and carboxylate moieties (see table 1).

With regard to claims 40, 42, Vera teaches an ECL reagent with Ruthenium bipyridine (see table 1).

4. Claims 34-35, 37, 40 and 42 are rejected under 35 U.S.C. 102(b) as being anticipated by Kuzmin et al (J. Photochem. Photobiol. A: Chem (1995) 87:43-54).

Kuzmin teaches a method for detecting an "analyte" in a sample composition (see page 44, column 2, where SDS micelles and the different micelle concentrations are the analytes) comprising the steps of:

(a) preparing an assay mixture comprising:

(i) said sample composition (see page 44, column 2, where SDS micelles and the different micelle concentrations are the analytes),

(ii) a first reagent comprising an ECL label having a chemical moiety that has electrochemical properties, which ECL label is capable of providing an observed ECL emission (see figure 1 and abstract, where Ruthenium bipyridine is used),

(iii) a second reagent having an ECL quenching moiety that, when in quenching contact with an ECL label, attenuates the observed ECL emission thereby providing a reduced ECL emission, said ECL quenching moiety comprising at least one benzene moiety (see table 1, where several different quinones were used)

(b) detecting a difference between the observed ECL emission and the reduced ECL emission, thereby confirming the presence of said analyte in the sample solution (see figure 3, where SDS micelles resulted in differential quenching).
With regard to claims 35, 37, Kuzmin teaches quinone moieties (see table 1).
With regard to claims 40, 42, Kuzmin teaches an ECL reagent with Ruthenium bipyridine (see abstract, table 1).

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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6. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

7. Claim 41 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kuzmin et al (J. Photochem. Photobiol. A: Chem (1995) 87:43-54).

Kuzmin teaches a method for detecting an "analyte" in a sample composition (see page 44, column 2, where SDS micelles and the different micelle concentrations are the analytes) comprising the steps of:

(a) preparing an assay mixture comprising:

(i) said sample composition (see page 44, column 2, where SDS micelles and the different micelle concentrations are the analytes),

(ii) a first reagent comprising an ECL label having a chemical moiety that has electrochemical properties, which ECL label is capable of providing an observed ECL emission (see figure 1 and abstract, where Ruthenium bipyridine is used),

(iii) a second reagent having an ECL quenching moiety that, when in quenching contact with an ECL label, attenuates the observed ECL emission

thereby providing a reduced ECL emission, said ECL quenching moiety comprising at least one benzene moiety (see table 1, where several different quinones were used)

(b) detecting a difference between the observed ECL emission and the reduced ECL emission, thereby confirming the presence of said analyte in the sample solution (see figure 3, where SDS micelles resulted in differential quenching).

With regard to claims 35, 37, Kuzmin teaches quinone moieties (see table 1).

With regard to claims 40, 42, Kuzmin teaches an ECL reagent with Ruthenium bipyridine (see abstract, table 1).

Kuzman teaches that Ruthenium and Osmium are known prior art equivalents, but does not exemplify the assay with Osmium (see page 51, column 2, paragraph 4).

It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to substitute osmium for ruthenium since Kuzmin teaches that these are known equivalents. As MPEP 2144.06 notes " Substituting equivalents known for the same purpose. In order to rely on equivalence as a rationale supporting an obviousness rejection, the equivalency must be recognized in the prior art, and cannot be based on applicant's disclosure or the mere fact that the components at issue are functional or mechanical equivalents. An express suggestion to substitute one equivalent component or process for another is not necessary to render such substitution obvious. In re Fout , 675 F.2d 297, 213 USPQ 532 (CCPA 1982)."

Allowable Subject Matter

8. Claims 30-33 are allowed.
9. Claims 43-59 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.
10. The following is a statement of reasons for the indication of allowable subject matter: Claims 30-33 and claims 43-59 are drawn to inventions in which the ECL label is attached to the analyte and the ECL quenching moiety is attached to a binding partner (which may be on the same molecule as the label). While there is prior art teaching the use of quenchers in this manner for fluorescent labels, such as the cited Tyagi paper which teaches fluorescence quenching on molecular beacons, there is no teaching or suggestion in either Kuzmin, Rajagopal or Vera that would provide even the slightest motivation to apply the phenolic quenching of the Ruthenium bipyridine ECL label to biological systems. In the absence of such motivation, no proper case of prima facie obviousness exists and the claims are novel and unobvious over the prior art.

Response to Arguments

11. Applicant's arguments filed November 21, 2005 have been fully considered but they are not persuasive.

Applicant's argument is that the references, such as Rajapol, Vera and Kuzmin do not teach a method in which an ECL emission is generated. This argument is not found persuasive because claim 34, unlike claim 30, for example, does not require any particular form of stimulation. Claim 30, as allowed, is limited to stimulation with

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electrodes. Claim 34 is open to any form of stimulation which results in emission by the label. Therefore, the emission and redox potential by the ruthenium 4-alkyl, 4'-methyl-2,2'-bipyridine in Vera will yield the same physical emission at 620 nm as when the dye is stimulated by electrodes.

This is consistent with the specification, which at page 49 indicates that a photomultiplier tube is used to detect light emission. The emission of the ruthenium 4-alkyl, 4'-methyl-2,2'-bipyridine will be at the same wavelength irrespective of how the label is stimulated and therefore, the prior art meets the current claim limitations, which simply require detection, but have no stimulation requirements such as those found in claim 30. In fact, Vera uses a red extended RCA 4840 photomultiplier for detection (see page 14, column 1), which is the same type of device used in the specification, which notes "a red sensitive photomultiplier tube is position directly above the working electrode so that light generated at or near the electrode is recorded (see page 49, lines 23-25 of the specification)."

Therefore, the claim rejections are maintained.

Conclusion

12. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the


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shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey Fredman whose telephone number is (571)272-0742. The examiner can normally be reached on 6:30-3:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on (571)272-0782. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Jeffrey Fredman
Primary Examiner
Art Unit 1637

1/11/05